

CLAIMS

The subject matter claimed is:

1. An in-the-ear hearing aid comprising:
 - (a) an earmold body configured for being inserted in an ear canal of a user of the hearing aid and for receiving hearing aid electronics, wherein a portion of the earmold body contacts the ear canal;
 - (b) the hearing aid electronics disposed in the earmold body; and
 - (c) a coating comprising a hydrogel disposed on the earmold body such that at least the portion of the earmold body that contacts the ear canal is coated with the hydrogel.
2. The hearing aid of claim 1 wherein the hydrogel expands as a soft pliant phase upon absorbing moisture and shrinks to a compact glassy phase upon drying.
3. The hearing aid of claim 2 wherein the hydrogel is polymerized from a mixture comprising a hydrogel monomer, a crosslinker, and an initiator.
4. The hearing aid of claim 3 wherein the initiator is a member selected from the group consisting of benzoin ethers, phenyl ketones, phosphine oxides, acetophenones, thioxanthenes, camphorquinones, ketocoumarins, peroxides, persulfates, azo compounds, and mixtures thereof.
5. The hearing aid of claim 3 wherein the initiator is a member selected from the group consisting of benzophenone, benzoin ethyl ether, 2,2, dimethoxy-2-phenyl-acetophenone, benzoyl cyclohexanol, *p*-hydroxybenzophenone, ammonium persulfate, and mixtures thereof.
6. The hearing aid of claim 3 wherein the initiator comprises a photoinitiator.
7. The hearing aid of claim 6 wherein the photoinitiator comprises an acetophenone.
8. The hearing aid of claim 7 wherein the acetophenone comprises 2,2-dimethoxy-2-phenyl-acetophenone.
9. The hearing aid of claim 3 wherein the mixture further comprises a foaming agent.

10. The hearing aid of claim 9 wherein the foaming agent is a member selected from the group consisting of alkali bicarbonates, alkali carbonates, fluorocarbon gases, pressurized gases, and mixtures thereof.

11. The hearing aid of claim 9 wherein the foaming agent comprises sodium bicarbonate.

12. The hearing aid of claim 3 wherein the mixture further comprises a foam stabilizing surfactant.

13. The hearing aid of claim 12 wherein the foam stabilizing surfactant is a member selected from the group consisting of polyether diblock copolymers, polyether triblock copolymers, non-ionic surfactants, anionic surfactants, cationic surfactants, and mixtures thereof.

14. The hearing aid of claim 12 wherein the foam stabilizing surfactant comprises an amphiphilic block copolymer.

15. The hearing aid of claim 14 wherein the amphiphilic block copolymer is an ABA triblock copolymer.

16. The hearing aid of claim 15 wherein the ABA triblock copolymer comprises a polyoxyethylene-polyoxypropylene-polyoxyethylene copolymer.

17. The hearing aid of claim 16 wherein the polyoxyethylene-polyoxypropylene-polyoxyethylene copolymer comprises about 60 to 80% by weight of polyoxyethylene.

18. The hearing aid of claim 16 wherein the polyoxyethylene-polyoxypropylene-polyoxyethylene copolymer comprises a polyoxypropylene block having a molecular weight of about 2500 to 4000.

19. The hearing aid of claim 3 wherein the mixture further comprises a filling agent.

20. The hearing aid of claim 19 wherein the filling agent is a member selected from the group consisting of metal oxides, silicon oxides, water-insoluble carbonates, water-insoluble sulfates, water-insoluble phosphates, and mixtures thereof.

21. The hearing aid of claim 19 wherein the filling agent comprises titanium dioxide.

22. The hearing aid of claim 19 wherein the filling agent comprises silicon dioxide.

23. The hearing aid of claim 19 wherein the filling agent comprises fumed silica.

5 24. The hearing aid of claim 19 wherein the filling agent comprises calcium carbonate.

25. The hearing aid of claim 3 wherein the mixture further comprises a foaming agent, foam stabilizing surfactant, filling agent, or mixture thereof.

10 26. The hearing aid of claim 3 wherein the hydrogel monomer is a member selected from the group consisting of hydroxyalkyl methacrylates, hydroxyalkyl acrylates, and mixtures thereof.

27. The hearing aid of claim 3 wherein the hydrogel monomer is a member selected from the group consisting of 2-hydroxyethyl methacrylate, 2-hydroxyethyl acrylate, N-vinyl pyrrolidone, methacrylic acid and salts thereof, 15 acrylic acid and salts thereof, vinyl acetate, hydroxypropyl methacrylate, and mixtures thereof.

28. The hearing aid of claim 3 wherein the hydrogel monomer comprises 2-hydroxyethyl methacrylate.

20 29. The hearing aid of claim 3 wherein the hydrogel monomer comprises methacrylic acid.

30. The hearing aid of claim 3 wherein the hydrogel monomer comprises N-vinyl pyrrolidone.

25 31. The hearing aid of claim 3 wherein the crosslinker is a member selected from the group consisting of diacrylates, dimethacrylates, diacrylamides, and mixtures thereof.

32. The hearing aid of claim 3 wherein the crosslinker is a member selected from the group consisting of ethylene glycol dimethacrylate, ethylene glycol diacrylate, poly(ethylene glycol)dimethacrylate, poly(ethylene glycol)diacrylate, N,N'-methylenebisacrylamide, and mixtures thereof.

30 33. The hearing aid of claim 3 wherein the crosslinker comprises a diacrylate.

34. The hearing aid of claim 33 wherein the diacrylate comprises ethylene glycol dimethacrylate.

35. An earmold configured for comprising a portion of an in-the-ear hearing aid comprising:

5 (a) an earmold body configured for being inserted in an ear canal of a user of the hearing aid and for receiving hearing aid electronics, wherein a portion of the earmold body contacts the ear canal; and

10 (b) a coating comprising a hydrogel disposed on the earmold body such that at least the portion of the earmold body that contacts the ear canal is coated with the hydrogel.

36. The earmold of claim 35 wherein the hydrogel expands as a soft pliant phase upon absorbing moisture and shrinks to a hard glassy phase upon drying.

15 37. The earmold of claim 36 wherein the hydrogel is polymerized from a mixture comprising a hydrogel monomer, a crosslinker, and an initiator.

38. The earmold of claim 37 wherein the initiator is a member selected from the group consisting of benzoin ethers, phenyl ketones, phosphine oxides, acetophenones, thioxanthenes, camphorquinones, ketocoumarins, peroxides, persulfates, azo compounds, and mixtures thereof.

20 39. The earmold of claim 37 wherein the initiator is a member selected from the group consisting of benzophenone, benzoin ethyl ether, 2,2, dimethoxy-2-phenyl-acetophenone, benzoyl cyclohexanol, *p*-hydroxybenzophenone, ammonium persulfate, and mixtures thereof.

25 40. The earmold of claim 37 wherein the initiator comprises a photoinitiator.

41. The earmold of claim 40 wherein the photoinitiator comprises an acetophenone.

42. The earmold of claim 41 wherein the acetophenone comprises 2,2-dimethoxy-2-phenyl-acetophenone.

30 43. The earmold of claim 37 wherein the mixture further comprises a foaming agent.

44. The earmold of claim 43 wherein the foaming agent is a member selected from the group consisting of alkali bicarbonates, alkali carbonates, fluorocarbon gases, pressurized gases, and mixtures thereof.

5 45. The earmold of claim 43 wherein the foaming agent comprises sodium bicarbonate.

46. The earmold of claim 37 wherein the mixture further comprises a foam stabilizing surfactant.

10 47. The earmold of claim 46 wherein the foam stabilizing surfactant is a member selected from the group consisting of polyether diblock copolymers, polyether triblock copolymers, non-ionic surfactants, anionic surfactants, cationic surfactants, and mixtures thereof.

48. The earmold of claim 46 wherein the foam stabilizing surfactant comprises an amphiphilic block copolymer.

15 49. The earmold of claim 48 wherein the amphiphilic block copolymer is an ABA triblock copolymer.

50. The earmold of claim 49 wherein the ABA triblock copolymer comprises a polyoxyethylene-polyoxypropylene-polyoxyethylene copolymer.

20 51. The earmold of claim 50 wherein the polyoxyethylene-polyoxypropylene-polyoxyethylene copolymer comprises about 60 to 80% by weight of polyoxyethylene.

52. The earmold of claim 50 wherein the polyoxyethylene-polyoxypropylene-polyoxyethylene copolymer comprises a polyoxypropylene block having a molecular weight of about 2500 to 4000.

25 53. The earmold of claim 37 wherein the mixture further comprises a filling agent.

54. The earmold of claim 53 wherein the filling agent is a member selected from the group consisting of metal oxides, silicon oxides, water-insoluble carbonates, water-insoluble sulfates, water-insoluble phosphates, and mixtures thereof.

30 55. The earmold of claim 53 wherein the filling agent comprises titanium dioxide.

56. The earmold of claim 53 wherein the filling agent comprises silicon dioxide.

57. The earmold of claim 53 wherein the filling agent comprises fumed silica.

5 58. The earmold of claim 53 wherein the filling agent comprises calcium carbonate.

59. The earmold of claim 37 wherein the mixture further comprises a foaming agent, foam stabilizing surfactant, filling agent, or mixture thereof.

10 60. The earmold of claim 37 wherein the hydrogel monomer is a member selected from the group consisting of hydroxyalkyl methacrylates, hydroxyalkyl acrylates, and mixtures thereof.

15 61. The earmold of claim 37 wherein the hydrogel monomer is a member selected from the group consisting of 2-hydroxyethyl methacrylate, 2-hydroxyethyl acrylate, N-vinyl pyrrolidone, methacrylic acid and salts thereof, acrylic acid and salts thereof, vinyl acetate, hydroxypropyl methacrylate, and mixtures thereof.

62. The earmold of claim 37 wherein the hydrogel monomer comprises 2-hydroxyethyl methacrylate.

63. The earmold of claim 37 wherein the hydrogel monomer comprises methacrylic acid.

20 64. The earmold of claim 37 wherein the hydrogel monomer comprises N-vinyl pyrrolidone.

65. The earmold of claim 37 wherein the crosslinker is a member selected from the group consisting of diacrylates, dimethacrylates, diacrylamides, and mixtures thereof.

25 66. The earmold of claim 37 wherein the crosslinker is a member selected from the group consisting of ethylene glycol dimethacrylate, ethylene glycol diacrylate, poly(ethylene glycol)dimethacrylate, poly(ethylene glycol)diacrylate, N,N'-methylenebisacrylamide, and mixtures thereof.

30 67. The earmold of claim 37 wherein the crosslinker comprises a diacrylate.

68. The earmold of claim 67 wherein the diacrylate comprises ethylene

glycol dimethacrylate.

69. A method for coating an earmold of an in-the-ear hearing aid comprising:

- (a) preparing a primary mold of a person's ear canal;
- (b) preparing a negative mold from the primary mold;
- (c) filling the negative mold at least partly with a hydrogel formulation;
- (d) polymerizing the hydrogel formulation for a controlled and sufficient

amount of time to form a thin hydrogel layer adjacent to the negative mold and leaving unpolymerized hydrogel formulation distal to the negative mold, and pouring off the unpolymerized hydrogel formulation;

(e) filling the negative mold having the thin hydrogel layer adjacent to the negative mold with an earmold-forming material;

(f) polymerizing the earmold-forming material for a controlled and sufficient amount of time to form a plastic layer adjacent to the thin hydrogel layer on the negative mold and leaving unpolymerized earmold-forming material distal to the thin hydrogel layer, and pouring off the unpolymerized earmold-forming material; and

(g) removing the plastic layer and thin hydrogel layer from the negative mold, thereby obtaining an earmold having a hydrogel coating disposed thereon.

70. The method of claim 70, wherein the hydrogel layer is about 0.1 to 3 millimeters thick.

71. The method of claim 69 wherein the earmold is about 0.5 to 5 millimeters thick.

72. A method for making a hearing aid earmold having a hydrogel coating disposed on at least a portion of the earmold comprising:

- (a) preparing a primary mold of a person's ear canal;
- (b) preparing a negative mold from the primary mold;
- (c) forming the earmold using the negative mold and removing the earmold from the negative mold;
- (d) disposing a layer of hydrogel formulation on the earmold; and
- (e) polymerizing the hydrogel formulation, thereby forming the hydrogel

coating.

73. The method of claim 72 wherein the earmold comprises a void for receiving the hydrogel formulation.

5 74. The method of claim 73 wherein the hydrogel formulation is disposed on the earmold by painting, brushing, spraying, or dipping.